

**REMARKS/ARGUMENTS**

Claims 1-31 and 38-54 are pending. By way of this Amendment, claims 32-37 are cancelled without prejudice or disclaimer and the specification and claims 1, 38 and 46 are amended. Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

Applicants appreciate the courtesies extended by Examiner Blizzard and SPE Yu to Applicants' undersigned representative during the personal interview conducted May 13, 2010. The points discussed during the interview are summarized in the remarks below and constitute Applicants record of the interview.

Claims 1-16, 20-31 and 38-54 were rejected under 35 U.S.C. §103(a) over Berthon-Jones et al. (U.S. Patent 6,123,071) in view of Thornton (U.S. Patent 6,571,798). The rejection is respectfully traversed.

Claim 1 recites a breathing arrangement for use between a patient and a structure to deliver a breathable gas to the patient. The breathing arrangement comprises a patient interface including a mouth covering assembly including a cushion structured to sealingly engage around an exterior of a patient's mouth in use, a nozzle assembly including a pair of nozzles structured to sealingly engage within nasal passages of a patient's nose in use, and a flexible element connecting the mouth covering assembly and the nozzle assembly.

The breathing arrangement further comprises at least one inlet conduit structured to deliver breathable gas into at least one of the mouth covering assembly and the nozzle assembly for breathing by the patient, and a headgear assembly removably connected to at least one of the mouth covering assembly and the nozzle assembly that, in use, follows two vectors, so as to

maintain the mouth covering assembly and the nozzle assembly in a sealed position on the patient's face.

As discussed during the interview, Berthon-Jones et al. disclose in column 5, lines 4-8, that it is usual to provide fastening of the mouth mask to the head of the patient by means of head straps (not shown). The head straps must be tensioned to apply a positive sealing force for the cushion 20 at all points of contact with the patient's face. As noted by the undersigned during the interview, Berthon-Jones et al. further disclose in column 6, lines 25-34, that in use of the composite mask 40, shown in Fig. 2, both the nasal cushion 44 and the mouth cushion 46 can be secured to the patient's head by means of head straps similar to those shown in published European Application 0 549 299 A2 (copy attached).

Published European Application 0 549 299 A2 discloses that conventional straps 6 keep a nose mask 1 retained on a patient 5. See, page 3, lines 36-37, of EP 0 549 299 A2. As further disclosed on page 3, lines 29-35, the mask 1 takes the form of a shell 2 of firm plastic which is shaped to fit over at least the nose region of the patient. A distendable membrane 7 is mounted on the shell 2 and forms a face contacting portion of the mask 1. The shell 2 and the membrane 7 together define a chamber which receives the patient's nose. The chamber communicates with an air or other breathable gas supply aperture to which a short length of supply tube 3 is connected.

In the second embodiment illustrated in Fig. 5 of EP 0 549 299 A2, the mask 21 is a nose mask and includes a substantially similar arrangement of straps 26 to retain the nose mask 21 in position. See page 4, lines 39-45. A third embodiment illustrated in Fig. 6 discloses a cap 29 with straps 36 provided for the patient in order to secure the mask 21.

As noted by the undersigned, Berthon-Jones et al. do not disclose or suggest, at least, a headgear assembly removably connected to at least one of the mouth covering assembly and the nozzle assembly that, in use, follows two vectors, so as to maintain the mouth covering assembly and the nozzle assembly in a sealed position on the patient's face. As also noted by the undersigned during the interview, published European Application 0 549 299 A2 fails to cure this deficiency of Berthon-Jones et al.

As noted by the undersigned during the interview, the conventional straps disclosed in published European Application 0 549 299 A2 are configured to apply a force to the nose mask 1 or 21 that seals the nose mask to the face of the patient. In other words, the conventional straps of published European Application 0 549 299 A2 are configured to provide a sealing force to a mask that extends across the bridge of the patient's nose, along the creases between the patient's cheeks and the patient's nose, and across the upper lip of the patient. In general, a mask such as a nasal mask as disclosed in published European Application 0 549 299 A2 is retained in a sealing relationship with a patient's face by headgear forces that are generally perpendicular to the plane of the patient's face. The headgear configuration shown in published European Application 0 549 299 A2 would not provide a vector to retain a nozzle assembly including a pair of nozzles structured to sealingly engage within nasal passages of a patient's nose, as recited in claim 1, because the vector required to retain a nozzle assembly sealingly engaged with the nasal passages of a patient's nose is not generally perpendicular to the plane of the patient's face, as the vector followed by the headgear in published European Application 0 549 299 A2.

During the interview, Examiner Blizzard stated that the vectors provided by the conventional straps of the headgear shown in published European Application 0 549 299 A2 would result in a single vector which is the result of all of the vectors provided by the

conventional straps of the headgear. While the conventional straps of the headgear disclosed in published European Application 0 549 299 A2 may result in a single resultant force applied to the nasal mask, each of the conventional straps, the strap connected to the bottom of the shell 2 and the strap connected to the supply tube 3, do follow a vector. However, neither vector followed by the conventional straps of the headgear of published European Application 0 549 299 A2 would maintain a nozzle assembly as recited in claim 1 in sealed position on the patient's face within nasal passages of a patient's nose in use.

During the interview, Examiner Blizzard also noted that the conventional straps of the headgear shown in published European Application 0 549 299 A2 includes a strap that extends from the upper strap across the top of the patient's head to the supply tube 3, as shown in Figs. 1 and 5. As noted by the undersigned, there is no disclosure or suggestion in published European Application 0 549 299 A2 that the strap across the top of the patient's head follows a vector so as to maintain a nozzle assembly in a sealed position on a patient's face, as recited in claim 1. As also noted by the undersigned during the interview, it is unlikely that the strap that extends across the top of the patient's head is configured to follow a vector as such a vector would tend to cause the nasal mask to be pulled up on the patient's face and against the bottom of the patient's nose, which would likely tend to cause discomfort to the patient and reduced effectiveness of the therapy.

Examiner Blizzard also stated during the interview that Thornton discloses all of the features of claim 1 with the exception of the headgear assembly. The undersigned respectfully disagreed, noting that Thornton does not disclose or suggest a mouth covering assembly including a cushion structured to sealingly engage around an exterior of a patient's mouth in use, as recited in claim 1. As noted by the undersigned during the interview, the venting seal 24 of

Thornton is not a cushion, as that term would be understood by one of ordinary skill in the art, and as is consistent with the use of that term in Applicants' specification. The venting seal 24 of Thornton thus does not correspond to the cushion of claim 1.

Moreover, as also noted by the undersigned during the interview, Thornton does not disclose or suggest a flexible element connecting the mouth covering assembly and the nozzle assembly, as recited in claim 1. Thornton clearly discloses that each embodiment of his invention is configured to be clamped to the connecting part 20 by providing the standard interface arm 22 through the clamp 32 of the nasal flange 26. The clamp 32 is not a flexible element as that term would be understood by one of ordinary skill in the art, and as used in Applicants' specification.

Furthermore, it is respectfully submitted that Thornton teaches away from the use of headgear assembly in column 7, lines 53-61. Thornton discloses that prior lip shields for preventing venting have required cumbersome and often intimidating head straps to secure the lip shield to the user's face, along with straps that wrap over their head and under the jaw to hold the user's jaw shut. Thornton discloses that despite these measures, prior art lip shields were still not able to achieve adequate lip competence in many cases and that his invention overcomes the problems and disadvantages of such techniques. One of ordinary skill in the art following the disclosure of Thornton clearly would have been led away from the provision of a headgear assembly to the device of Thornton.

As the combination of Berthon-Jones et al and Thornton fails to include all of the features of claim 1, and as Thornton actually teaches away from the invention recited in the claim, the combination fails to present a *prima facie* case of obviousness.

Independent claims 38 and 46 each recite, *inter alia*, a cushion structured to sealingly engage around an exterior of a patient's mouth in use, the cushion including a side wall structure to be removably attached to a frame, a rim extending away from the side wall, and a membrane provided to substantially surround the rim. The patient interface further comprises a pair of nozzles to sealingly engage within nasal passages of a patient's nose in use, each of the nozzles including a conduit that extends from the side wall of the cushion and supports each nozzle.

As discussed during the interview, Thornton clearly does not disclose or suggest a pair of nozzles structured to sealingly engage within nasal passages of a patient's nose in use, each of the nozzles including a conduit that extends from the side wall of the cushion and supports each nozzle. As also discussed during the interview, even assuming it would have been obvious to combine Thornton with Berthon-Jones et al., which Applicants do not concede, the combination would not have resulted in the inventions of claims 38 and 46.

Claims 2-16, 20-31, 39-45 and 47-54 recite additional features and are allowable for the same reasons discussed above with respect to claims 1, 38 and 46, respectively, and for the additional features recited therein.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) over Berthon-Jones et al. in view of Thornton are respectfully requested.

Claims 17-19 were rejected under 35 U.S.C. §103(a) over Berthon-Jones et al. in view of Thornton and further in view of Trimble (U.S. Patent 4,782,382). The rejection is respectfully traversed.

Claims 17-19 recite additional features and are allowable for the same reasons discussed above with respect to claim 1 and for the additional features recited therein. It is also respectfully submitted that Trimble fails to cure the deficiencies of the combination of

Berthon-Jones et al. and Thornton and that even assuming it would have been obvious to combine the references, which Applicants do not concede, the combination would not have resulted in the claimed inventions.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) over Berthon-Jones et al. in view of Thornton and Trimble are respectfully requested.

In view of the above amendments and remarks, Applicants respectfully submit that all of the claims are allowable and the entire application is in condition for allowance.

The Commissioner is authorized to charge the undersigned's deposit account #14-1140 in whatever amount is necessary for entry of these papers and the continued pendency of the captioned application.

Should the examiner believe that anything further is desirable to place the application in condition for allowance, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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Attachment:  
EP 0 549 299 A2